

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: WAVE 4 CASES LISTED IN MOTION EXHIBIT A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**DEFENDANTS' REPLY IN SUPPORT OF MOTION TO EXCLUDE
THE OPINIONS AND TESTIMONY OF DR. PAUL J. MICHAELS, M.D.**

Defendants Ethicon, Inc., Ethicon LLC, and Johnson & Johnson (collectively, “Ethicon”) submit this Reply in Support of their Motion to Exclude the Opinions and Testimony of Dr. Paul J. Michaels, M.D. (“Motion”).

Plaintiffs’ Response to Defendant Ethicon’s Motion to Exclude the Opinions and Testimony of Paul J. Michaels [ECF No. 3792] (“Response”) fails to address Ethicon’s numerous arguments regarding the lack of reliability of Dr. Michaels’s opinions. Instead, Plaintiffs seek to avoid the substance of Ethicon’s Motion by claiming that Dr. Michaels is “qualified” to offer opinions in this litigation; mischaracterizing Ethicon’s positions and the scientific literature; and erroneously portraying Ethicon’s arguments as reflecting a mere “difference of opinion” among the parties’ experts.

In addition, throughout the Response, Plaintiffs repeatedly substitute invective for analysis, and resort to asserting that Ethicon has made misrepresentations to this Court. *See, e.g.,*

Resp. at 2, 5, 7, 11–13. Plaintiffs’ allegations regarding Ethicon’s candor toward this Court are inappropriate and entirely unsubstantiated.

The Court should exclude the opinions and testimony of Dr. Paul Michaels for all of the reasons detailed below and in Ethicon’s Motion.

I. Dr. Michaels’s Opinions Regarding Degradation Are Unreliable.

A. Ethicon Challenges the Reliability of Dr. Michaels’s Degradation Opinions, Not His Qualifications as a Pathologist.

In its Motion, Ethicon challenged Dr. Michaels’s degradation opinions as unreliable on numerous grounds. *See* Mot. at 2–12. Throughout the Response, however, Plaintiffs repeatedly claim that Dr. Michaels is “qualified” to testify at trial. *See* Resp. at 3–6, 13–15. Plaintiffs ignore the distinction between an expert’s qualifications and the reliability of his opinions. As this Court recently explained:

Even if an expert is highly qualified, an analysis of the reliability of that expert’s methodology is required. *See Daubert*, 509 U.S. at 597 (explaining that the Federal Rules of Evidence “do assign the trial judge the task of ensuring that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand”). Qualifications alone do not guarantee reliability. *See Hoffman v. Monsanto Co.*, No. 2:05-cv-00418, 2007 WL 2984692, at *3–5 (S.D. W. Va. Oct. 11, 2007) (excluding opinions of a “very qualified” expert because the basis for the testimony was unreliable). “[I]n order to qualify as ‘scientific knowledge,’ an inference or assertion must be derived by the scientific method.” *Daubert*, 509 U.S. at 590.

Trevino v. Boston Sci. Corp., No. 2:13-CV-01617, 2016 WL 2939521, at *12 n.8 (S.D. W. Va. May 19, 2016).

Plaintiffs have erected a straw man to the extent they argue that Dr. Michaels is qualified to testify in this litigation. The argument raised by Ethicon is that Dr. Michaels’s opinions are unreliable.

B. Dr. Michael's Degradation Opinions Are Unreliable Due to Lack of Testing or Any Other Indicia of Reliability.

In its Motion, Ethicon argued that, as made clear by the Fourth Circuit's recent decision in *Nease v. Ford Motor Co.*, 848 F.3d 219 (4th Cir. 2017), Dr. Michael's degradation opinions are unreliable due to lack of any testing to verify his degradation theories. Mot. at 3–4. Plaintiffs try to dismiss the importance of *Nease* on the grounds that “[e]ven the *Nease* Court recognized that ‘Daubert is a flexible test and no single factor, even testing, is dispositive.’” Resp. at 6 n.1 (quoting *Nease*, 848 F.3d at 232). However, *Nease* recognized that testing was an “especially important factor for guiding a court in its reliability determination.” 848 F.3d at 231.

Here, as in *Nease*, lack of testing undermines the reliability of Dr. Michaels's degradation opinions. Dr. Michaels could have run several tests, experiments, or studies to confirm his degradation opinions, but he failed to do so. *See* Mot. at 4–5. As it stands, his opinion that Prolene degrades *in vivo* is simply an untested hypothesis and “it thus is not knowledge.” *Nease*, 848 F.3d at 231 (quoting *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 670 (6th Cir. 2010)).

The other *Daubert* reliability factors do not support the admissibility of Dr. Michaels's degradation opinions. His hypothesis has never been subjected to peer review; as explained below and in Ethicon's Motion, the literature that Dr. Michaels relies on does not actually support his degradation opinions. Further, Plaintiffs do not offer any information concerning the potential error rate of Dr. Michaels's degradation opinions. Thus, Dr. Michaels' degradation opinions—like the opinions at issue in *Nease*—cannot satisfy *Daubert's* reliability requirement. *See Nease*, 848 F.3d at 232 (finding that expert's opinion could not survive reliability prong because it was untested, had not been subjected to peer-review, and there was no way to assess its potential error rate).

C. Plaintiffs Misunderstand Ethicon's Arguments Regarding Dr. Michaels's General Experience as a Pathologist, Which Does Not Provide a Reliable Foundation for His Degradation Opinions.

In its Motion, Ethicon provided several reasons why Dr. Michaels's degradation opinions are unreliable, including the fact that Dr. Michaels's general experience as a pathologist does not constitute a reliable foundation for his opinions. Mot. at 2–12. Plaintiffs responded to Ethicon's arguments by claiming that “Ethicon . . . argues that Dr. Michaels' degradation opinions are based solely on his general pathology experience.” Resp. at 4; *see also id.* at 3–7.

As Ethicon's Motion plainly shows, Dr. Michaels's lack of relevant experience is only one of the reasons why his degradation opinions are unreliable. *See* Mot. at 2–12. Plaintiffs appear to be oblivious of this fact, even though they observe that Ethicon spent several pages explaining why the scientific literature on which Dr. Michaels relies does not support his opinions. *See* Resp. at 4.

In addition, nothing in Plaintiffs' Response demonstrates that any of Dr. Michaels's experience as a pathologist provides a reliable basis for him to opine that the Prolene in Ethicon mesh products degrades *in vivo*. *See* Resp. at 3–7. For instance, Plaintiffs seek to bolster Dr. Michaels's experience by claiming that he examined more mesh explants prior to litigation than two of Ethicon's experts. Resp. at 1–2. Plaintiffs overlook the fact that neither of Ethicon's two experts seeks to inform a jury that the Prolene in Ethicon mesh products degrades *in vivo* without a reliable scientific basis. Plaintiffs also forget that Dr. Michaels did not present any evidence that these meshes were composed of Prolene, and that he did not produce any of the samples or pathology reports to Ethicon. Mot. at 6.

Similarly, Plaintiffs dispute Ethicon's argument that Dr. Michaels's experience as a pathologist does not provide a reliable basis for his opinions that Prolene becomes embrittled and loses mechanical properties because he has only grossly examined 24 mesh explants. *See* Resp.

at 3–4; Mot. at 4–5. The crux of Plaintiffs’ argument is that one excerpt of Dr. Michaels’s testimony suggests that he also examined those 24 meshes under a microscope. Resp. at 3–4. Plaintiffs’ argument is a distinction without difference.

Plaintiffs appear to misconstrue Ethicon’s position. Ethicon’s arguments regarding Dr. Michaels’s pre-litigation analysis of 24 meshes pertain to his opinions about the alleged embrittlement and reduction in mechanical properties of Prolene. *See* Mot. at 4–5.¹ Ethicon showed that Dr. Michaels testified that he grossly examined only half of the 24 mesh explants before they were fixed in formalin, a chemical that causes specimens to become rigid and reduces mechanical properties. *Id.* at 6. Ethicon also explained that Dr. Michaels did not conduct any sort of objective analysis using a reliable methodology to assess embrittlement and mechanical properties. *Id.* at 4–6. Rather, Dr. Michaels’s own testimony shows that his analysis was limited to his subjective assessment as to how the mesh “felt” after explantation, his “experience” was limited to handling that subset of his 24-mesh pool. *Id.*; *see also* Mot. Ex. B, Michaels 6/18/16 General Dep. 66:17–67:8. As Ethicon explained in its Motion, Dr. Michaels’s methods—consisting of his memory of how meshes “felt,” in some cases many years ago—are not consistent with sound scientific principles. Mot. at 5–6.

¹ Plaintiffs also claim that Ethicon “blatantly misrepresent[s] Dr. Michaels’ deposition testimony when they argue ‘Dr. Michaels testified that his embrittlement opinion is based solely on his examination of the gross specimens in the past[.]’” Resp. at 7. But Ethicon simply quoted Dr. Michaels’s testimony when he was asked at deposition to explain the work he had done to study embrittlement and crack formation. *See* Mot. at 5 (citing Mot. Ex. B, Michaels 6/18/16 General Dep. 64:14–65:10). Moreover, despite claiming that “[a] clear reading of Dr. Michaels’ expert report and deposition transcript tells a different story,” Plaintiffs failed to specify any part of his report or testimony demonstrating another basis for Dr. Michaels’s opinion that degraded Prolene becomes embrittled such that it loses mechanical properties. *See* Resp. at 7–8.

Plaintiffs' Response fails to show that any of Dr. Michaels's experience as a pathologist constitutes a reliable foundation for his opinion that Prolene degrades in the pelvic floor. Accordingly, the Court should exclude Dr. Michaels's degradation opinions as unreliable.

D. Plaintiffs Failed to Identify Any Relevant Scientific Literature Supporting Dr. Michaels's Opinion That the Prolene in Ethicon Mesh Products Degrades *In Vivo*.

i. Plaintiffs Only Point to Studies and Tests That Do Not Actually Support Dr. Michaels's Degradation Opinions.

Plaintiffs attempt to show that Dr. Michaels's opinions are supported by scientific literature by pointing to certain studies and internal Ethicon tests, and string citing to passages from Dr. Michaels's deposition which supposedly identify the studies on which his opinions are based. *See Resp.* at 8. But none of the studies and tests to which Plaintiffs point actually supports Dr. Michaels's degradation opinions.

Of the 17 excerpts to which Plaintiffs repeatedly cite as evidence that Dr. Michaels based his opinions on scientific literature, all but three fail to actually identify any scientific literature at all. *See Mot. Ex. B, Michaels* 6/18/16 General Dep. 15:15–16:18; 20:12–21:1; 39:2–11; 39:21–40:12; 48:9–49:10; 49:17–18; 52:4–12; 60:14–20; 63:2–12; 64:9–65:10; 72:15–18; 76:14–77:13; 82:5–19.

The studies and tests identified in the three remaining excerpts, as well as those expressly cited in the Response, are the very same documents that, as the Motion explained, fail to support Dr. Michaels's opinion that the Prolene in Ethicon mesh products degrades *in vivo*. *See Resp.* at 8 (listing six studies, each of which is addressed in the Motion on pages 8–11, and discussing an internal Ethicon test, which is addressed on pages 7–8 of the Motion); *see also Mot. Ex. B, Michaels* 6/18/16 General Dep. 57:9–24 (identifying same studies and tests addressed in

Ethicon's Motion on pages 7–12); 65:21–66:5 (pointing to Clave study addressed in Ethicon's Motion); 103:11–104:4 (discussing Hill study addressed in Ethicon's Motion).

In other words, Plaintiffs failed to identify any scientific literature that actually stands for the proposition that the Prolene in Ethicon mesh products degrades in the human body. Despite Plaintiffs' efforts to distract the Court through voluminous citations, they cannot change the contents of those studies and tests or the underlying science at issue.

ii. Plaintiffs Misunderstand Ethicon's Arguments and the Scientific Literature.

Plaintiffs' efforts to rebut Ethicon's explanation of the literature on which Dr. Michaels relies serves only to highlight Plaintiffs' misunderstanding of those studies and tests, as well as the underlying science at issue. *See* Resp. at 11–12.

- Costello – Plaintiffs claim that Ethicon “disingenuous[ly]” argues that the Costello study shows that Prolene Soft does not degrade even though the Prolene Soft was “used only as a control.” Resp. at 11. Plaintiffs apparently misunderstand Ethicon's Motion, which explained that the study involved three hernia meshes including Ethicon's Proceed mesh. Mot. at 8–9. Plaintiffs cannot dispute that Costello reported no signs of degradation on the Proceed mesh. *Id.*

In asserting that Costello “provides strong evidence that polypropylene-based mesh devices” degrade *in vivo*, (Resp. at 11), Plaintiffs repeat Dr. Michaels's error by assuming that the study's findings regarding a Bard mesh apply to the Prolene used in Ethicon mesh products.

- Wood – Plaintiffs do not dispute Ethicon's observation that there was no indication that the Wood study addressed Prolene or even mesh used in the pelvic floor. Resp. at 11. Instead, Plaintiffs declare—with no analysis or explanation—that the Wood study “provides strong support that polypropylene-mesh degrades *in vivo*.” *Id.* In so doing, Plaintiffs ignore the scientific significance of having evidence that actually addresses the substance at issue—here, Prolene.
- Jongebloed – Plaintiffs overlook four salient facts in arguing that Jongebloed “provides strong support that Ethicon's Prolene-based products under[go] *in vivo* degradation.” *See* Resp. at 11. Specifically, Plaintiffs seem not to understand that: (i) “ocular” sutures are implanted in the eye; (ii) by virtue of their placement, ocular sutures are exposed to ultraviolet radiation; (iii) all forms of polypropylene are known to degrade when exposed to ultraviolet radiation; and (iv) the Prolene in Ethicon

mesh products is not exposed to ultraviolet radiation because it is implanted in the pelvic floor. Resp. at 11. In arguing that Jongebloed nonetheless supports Dr. Michaels's degradation opinions in this case, Plaintiffs disregard scientific facts.

- Mary – Plaintiffs fail to address any of Ethicon's arguments regarding the Mary study. Resp. at 11–12. Indeed, Plaintiffs find it “incredibl[e]” that Ethicon would dispute the reliability of a study that has been shown to have significant methodological flaws. *Id.* Rather than responding to any of Ethicon's methodological arguments, Plaintiffs simply assert their talismanic refrain the study “provides very strong evidence that Ethicon's Prolene products degrade *in vivo*.” *Id.* Plaintiffs ignore the fact that their *ipse dixit* is no more persuasive than an expert's.
- Liebert – In arguing that Liebert “demonstrates that inadequately protected polypropylene fibers will degrade *in vivo*,” *Id.* Plaintiffs ignore the fact that Prolene is protected by a proprietary antioxidant package. For this reason, as explained in Ethicon's Motion, Liebert does not support Dr. Michaels's opinion that the Prolene in Ethicon mesh products degrades *in vivo*. Mot. at 10–11.

In sum, Plaintiffs' incantations that these studies provide “strong evidence” or “strong support” for Dr. Michaels's opinions are pure *ipse dixit* that should be rejected by this Court.

In arguing that the Court need not determine whether Dr. Michaels's opinions are correct, Plaintiffs miss the central thrust of Ethicon's argument. Resp. at 12. To be clear, Ethicon's position is not merely that Dr. Michaels's conclusions are incorrect. Rather, Ethicon has shown that the studies on which Dr. Michaels relies in opining that the Prolene used in Ethicon mesh products degrades *in vivo* do not provide reliable scientific evidence for that proposition. *See* Mot. at 8–11. For this reason, Dr. Michaels's opinions themselves cannot be said to be reliable.

iii. Plaintiffs Fail to Show That Any of Ethicon's Internal Documents Support Dr. Michaels's Degradation Opinions.

Although Plaintiffs claim that Dr. Michaels bases his degradation opinions on internal Ethicon documents, Plaintiffs fail to explain how any such documents actually support his opinions. *See* Resp. at 12–13. Instead, Plaintiffs allege that Ethicon “misstate[s] and mischaracterize[s] evidence in this case.” *Id.* at 12. Plaintiffs notably fail to specify any mischaracterization of Ethicon's internal documents. *See id.* And rather than focusing on the

issue at hand, Plaintiffs veer off on a tangent about Ethicon's alleged misrepresentation of opinions offered by their expert, Dr. Jordi. *See id.* at 12–13.

Specifically, Plaintiffs charge that Ethicon “misrepresent[ed]” Dr. Jordi's testimony in which he “conceded that a decrease in molecular weight of an explanted polypropylene specimen is required to prove degradation.” *Id.* at 12. But the passage of Dr. Jordi's deposition to which Ethicon cited states as follows:

Q. Until you have the opportunity to test as you've described, the fact that your molecular weight testing does not show a significant difference in molecular weight suggests that there's no degradation of the polypropylene. That's the best scientific conclusion you can reach in this data, isn't that true?

A. It's one of the conclusions, yes.

Mot. Ex. G, Jordi 10/30/13 Dep. 173:25–174:8. This is the precise proposition for which Ethicon cited Dr. Jordi's testimony. *See* Mot. at 11.

Unable to substantiate their allegation through Dr. Jordi's testimony, Plaintiffs employ a bait-and-switch by referring to a rebuttal report issued by Dr. Jordi *after* he made his concession during his October 30, 2013 deposition. *See* Pl. Resp. Ex. G, Jordi Rebuttal Report (Nov. 5, 2013). Despite Dr. Jordi's *post hoc* attempt to rehabilitate his testimony, Plaintiffs cannot undo his concession.

Plaintiffs' allegation is further undermined by the fact that Plaintiffs' other experts have similarly conceded that oxidative degradation causes a reduction in molecular weight. For instance, Dr. Jimmy Mays, a polymer scientist for Plaintiffs in this litigation, testified as follows:

Q. But, Doctor, for oxidative degradation to occur, there must be a loss of molecular weight; correct?

A. Yes, when oxidative degradation of polypropylene occurs, there is degradation of molecular weight.

Mot. Ex. F, Mays 3/2/2016 Dep. 79:18–22. Plaintiffs may not like the testimony provided by their experts, but they cannot dismiss it as a mere fabrication by Ethicon.

Finally, Plaintiffs once again miss the mark in suggesting that Ethicon’s argument boils down to a mere disagreement with Dr. Michaels’s opinions. Resp. at 13. Ethicon’s position is not that Dr. Michaels reached the wrong conclusion, but that his choice to base his opinion on documents that do not actually stand for the propositions he asserts renders his opinions unreliable. *See* Mot. at 7–12.

E. Plaintiffs Failed to Demonstrate That Dr. Michaels Used a Reliable Methodology in Forming His “Bark” Opinions.

In its Motion, Ethicon argued that Dr. Michaels had failed to properly disclose any opinions in Wave 4 concerning the use of polarized light microscopy to detect a “bark” layer allegedly composed of degraded Prolene is unreliable. Mot. at 7. In their Response, Plaintiffs claim that Dr. Michaels “did disclose this opinion in his Wave 3 report and even provided polarized light microscopy images to support his opinion and to illustrate this observation.” Resp. at 9–10. However, the only portion of Dr. Michaels’s Wave 3 report that Plaintiffs cite is a single micrograph supposedly showing a degradation bark. *See* Resp. at 9 (citing Resp. Ex. A, Michaels Report, at 26). This single reference to a degradation bark does not satisfy Rule 26’s disclosure requirements, as it provides no clear indication as to which opinions Dr. Michaels will offer at trial about the bark or the bases for these opinions.

Further, Plaintiffs cannot establish the reliability of Dr. Michaels’s “bark” opinions as disclosed in his Wave 2 report. Mot. at 7–8. Specifically, Ethicon explained that this methodology is fundamentally flawed for the same reasons discussed in Ethicon’s Motion to exclude the opinions of Dr. Vladimir Iakovlev, on whose work Dr. Michaels bases his approach. *Id.* at 7. Ethicon also showed that the internal Ethicon test from 1984 on which Dr. Michaels

relies suffers from the same fatal flaws as Dr. Iakovlev's opinions—namely, it did not validate the underlying theory that degraded Prolene would actually hold histological stain. *Id.* at 8.

None of Plaintiffs' responses withstand scrutiny. For instance, Plaintiffs claim that Ethicon argues not that Dr. Michaels's methodology is unreliable, but only that his "*conclusions* of degradation 'bark' have [not] been previously published in the medical and scientific literature." Resp. at 10 (emphasis in original). Plaintiffs' Response makes no sense, as Ethicon's challenge is *purely* methodological. *See* Mot. at 7–8.

Plaintiffs seek to evade Ethicon's methodological challenge by pointing to a distinguishable prior ruling, and claiming that the results in this case should be no different. *See* Resp. at 10 (citing *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *70 (S.D. W. Va. July 8, 2014)). Plaintiffs ignore the fact that the evidence on which Ethicon bases its arguments that the methodology employed by Drs. Michaels and Iakovlev is unreliable—including Dr. MacLean's testing that invalidates their central hypothesis—was not before the Court when it issued its decision in *Edwards*.

Despite Plaintiffs' repeated assertion that Dr. Michaels's methodology is based on peer-reviewed literature, Plaintiffs notably fail to identify even one study establishing the validity of Dr. Michaels's approach. *See* Resp. at 9–11. Similarly, although Plaintiffs repeatedly claim that Dr. Michaels's approach was used by Ethicon's own scientists, (*see id.*), Plaintiffs ignore the fact that Ethicon explained that this study is methodologically flawed, (*see* Mot. at 7–8).

Plaintiffs effectively ask this Court to limit Ethicon's state of scientific knowledge to a test that took place 32 years ago without regard for advances in scientific methods and understanding, including the fact that the hypothesis underlying the testing has now been disproven. The Court should reject Plaintiffs' invitation to ignore the scientific method, which

necessarily requires “subjecting testable hypotheses to the crucible of experiment in an effort to disprove them.” *United States v. Bynum*, 3 F.3d 769, 773 (4th Cir. 1993).

II. Dr. Michaels’s Opinions That the Degradation of the Prolene in Ethicon Mesh Products Causes Clinical Complications.

In its Motion, Ethicon challenged the reliability of Dr. Michaels’s opinion that the alleged *in vivo* degradation of Prolene causes clinical complications in patients implanted with Ethicon mesh products. Mot. at 11–12. Ethicon showed that Dr. Michaels’s general experience as a pathologist does not provide a reliable foundation for his opinions regarding complications allegedly caused by degradation. *Id.* at 3, 11–12. Ethicon also explained that Dr. Michaels was unable to identify, either at deposition or in his expert report, any scientific literature that actually supports his contention that degradation causes clinical complications. *Id.* at 11–12.

Rather than respond to Ethicon’s arguments regarding the reliability of Dr. Michaels’s opinions, Plaintiffs resort to asserting that “Ethicon is either purposefully or carelessly ignorant of this Court’s prior orders” regarding other pathologists.² Resp. at 13. Plaintiffs then veer down the rabbit hole by spending two pages arguing that Dr. Michaels is “qualified” to opine about the clinical complications caused by the alleged degradation of Prolene. *Id.* at 13–15.

Once again, Plaintiffs have conflated Dr. Michaels’s qualifications with the reliability of his opinions. *See Trevino*, 2016 WL 2939521, at *12 n.8 (explaining distinction between qualifications and reliability). Nothing in Plaintiffs’ lengthy recitation of Dr. Michaels’s *qualifications* as a pathologist establishes that his opinions regarding clinical complications caused by degradation are *reliable*.

² Ethicon is fully aware of this Court’s prior orders regarding other pathologists in pelvic mesh litigation. Ethicon respectfully submits that this Court has not yet ruled as to the reliability of Dr. Michaels’s opinions in this particular wave of cases.

Plaintiffs' sole effort to address Ethicon's arguments regarding reliability is their assertion that Dr. Michaels "cited to peer-reviewed publications in his expert report that support" his opinions regarding clinical complications. *See* Resp. at 15 (citing Michaels Report at 6). But Plaintiffs again point to the same studies and tests that, as Ethicon has explained, do not support Dr. Michaels's opinions. *See* Mot. at 8–11; *see also supra* at § I.D. Moreover, most of the studies and tests do not address complications at all.

The only studies Dr. Michaels cites regarding the complications allegedly caused by degradation are the Mary and Clave papers. *See* Michaels Report at 6. But nothing in either of these studies stands for the proposition that the degradation of Prolene causes clinical complications. *See* Mot. Ex. O, Clave; Mot. Ex. R, Mary. Indeed, given that the Clave study could not even confirm that the polypropylene under examination actually degraded, it cannot be said that the study proves that degradation causes clinical complications. *See* Mot. at 9 (quoting Mot. Ex. O, Clave at 266). Similarly, the numerous methodological flaws in the Mary study deprive it of validity. *See* Mot. at 10.

Ethicon does not, as Plaintiffs suggest, merely disagree as to the proper interpretation of a study, or claim that Dr. Michaels could not recall the name of a study at deposition. *See* Resp. at 15. Rather, Ethicon's position is that the scientific literature—held out by both Plaintiffs and Dr. Michaels as the basis for his opinion that degradation causes complications—clearly does not say what Plaintiffs and Dr. Michaels claim it does. Thus, Ethicon submits that Dr. Michaels's opinions based on that scientific literature are unreliable.

III. Plaintiffs Failed to Identify Any Reliable Basis for Dr. Michaels's Opinions Regarding the Alleged Contraction, Shrinkage, and Deformation of Ethicon Mesh Products.

As Ethicon explained in its Motion, Dr. Michaels's opinions regarding the contraction, shrinkage, and deformation of Ethicon mesh products are unreliable because he failed to follow

the well-established methodology used by pathologists for determining how a specimen was oriented *in vivo*. Mot. at 12–14. Ethicon also showed that Dr. Michaels was aware that mesh explants change shape following excision from the body. *Id.* at 13. Ethicon further explained that Dr. Michaels failed to consider the effects of the formalin used in the sample preparation process on the mesh explant. *Id.*; *see also* Mot. Ex. B, Michaels 6/18/16 General Dep. 44:1–14 (admitting that he did not read studies regarding the effect of formalin fixation on mesh explants).

Plaintiffs do not dispute the fact that Dr. Michaels did not follow the standard methodology used by pathologists to determine the *in vivo* orientation of specimens. Rather, they respond by claiming that Ethicon’s “argument fundamentally misunderstands Dr. Michaels’s role as a diagnostic anatomical pathologist[.]” *See* Resp. at 15–16. Plaintiffs appear to take the position that diagnostic anatomical pathologists either do not consider the *in vivo* orientation of the specimens they examine, or do not follow the standard methodology discussed in the literature identified in Ethicon’s Motion. Regardless, Plaintiffs identify no medical authority for their assertion, which is simply untrue. *See* Mot. at 13 (discussing standard orientation methodology).

Plaintiffs then claim that “Dr. Michaels uses ‘standard histology techniques’” in his analysis based on his testimony that pathologists “can identify when there are folds in the tissue as opposed to something that is occurring biologically or pathologically.” Resp. at 16. Yet, neither Plaintiffs nor Dr. Michaels identify those methods. Indeed, nothing in Plaintiffs’ Response or Dr. Michaels’s expert report or testimony shows that he followed any methodology whatsoever to ascertain the *in vivo* orientation of the mesh explants about which he seeks to

opine. For this reason, as Ethicon explained in its Motion, Dr. Michaels’s opinions that mesh contracts, shrinks, or deforms in the human body is pure speculation. Mot. at 12–14.

Despite their assertion that Dr. Michaels’s opinions are “based on everything,” (Resp. at 16), including certain peer-reviewed publications, Plaintiffs cannot obscure the fact that Dr. Michaels failed to follow a reliable methodology in opining that the mesh explants at issue in this litigation contract, shrink, and deform in the human body. For this reason, Dr. Michaels should not be permitted to opine that any of the mesh explants he examined in this litigation contracted, shrunk, or deformed *in vivo*.

IV. Dr. Michaels’s Opinions Regarding Complications Are Unreliable.

A. Plaintiffs Failed to Show That Dr. Michaels’s Opinion That Ethicon Mesh Products Cause Inflammation That Results in Pain Is Reliable.

Plaintiffs claim that Ethicon “mischaracterize[s] Dr. Michaels’s testimony by suggesting he does not understand mechanisms of inflammatory response.” Resp. at 16. Plaintiffs misstate Ethicon’s argument.

As the Motion makes abundantly clear, Ethicon’s position is that Dr. Michaels’s testimony demonstrates that he cannot explain how any inflammation allegedly due to Ethicon mesh products causes patients to experience pain. Mot. at 14–16. Indeed, Ethicon pointed out that Dr. Michaels offers nothing but speculation as to how inflammation *may* have caused pain. *Id.* Ethicon also observed that Dr. Michaels could not cite any authority supporting his opinion that the mere presence of inflammation is a sufficient basis to conclude that the patient experienced pain. *Id.*

In addition, Ethicon showed that the only study Dr. Michaels could identify—the Hill study—actually contradicts his opinions, and that his efforts to undermine the Hill study’s findings made no sense. *Id.* at 15–16. Tellingly, Plaintiffs made no effort to rebut any of

Ethicon’s arguments showing that Dr. Michaels’s criticisms of the Hill study are baseless. *See* Resp. at 16–18.³

Despite Plaintiffs’ suggestion to the contrary, Ethicon’s arguments flow from Dr. Michaels’s own words. Ultimately, notwithstanding Plaintiffs’ assertion that Dr. Michaels is “eminent[ly] qualifi[ed]” to opine on the complications allegedly caused by Ethicon mesh products, (Resp. at 17), nothing in Plaintiffs’ Response shows that his opinions are reliable, *see Trevino*, 2016 WL 2939521, at *12 n.8 (explaining distinction between qualifications and reliability).

B. Dr. Michaels’s Failure to Follow a Proper Scientific Methodology Shows That His Opinion That Ethicon Mesh Products Cause Pain Is Unreliable.

In response to Ethicon’s arguments that Dr. Michaels’s opinions regarding pain are unreliable and methodologically unsound, (Mot. at 14–17), Plaintiffs fail to address the substance of Ethicon’s position, (*see* Resp. at 16–19). Instead, Plaintiffs again claim that Dr. Michaels’s opinions are supported by peer-reviewed literature. Resp. at 18. But Plaintiffs fail to identify a single study which stands for the proposition that the presence of a nerve in scar tissue or near mesh provides an adequate basis for concluding that the patient suffered from pain.

In arguing that “Dr. Michaels has provided actual proof” of his opinions “in the form of pathology slides,” Plaintiffs reveal that they misunderstand the point of Ethicon’s argument. *See id.* at 19. As the Motion clearly explains, the methods used by Dr. Michaels—including the use

³ In suggesting that the Hill study is inapposite, Plaintiffs appear to forget that two of their experts—Drs. Klosterhalfen and Klinge—previously reported findings consistent with the Hill study in the context of hernia mesh. Specifically, Drs. Klosterhalfen and Klinge explained that there is “little difference in inflammatory response in mesh removed for recurrence or chronic pain, contradicting the possibility of a specific tissue reaction as an underlying cause for either complication.” Reply Ex. HH, B. Klosterhalfen, U. Klinge, *et al.*, *Influence of Implantation Interval on the Long-Term Biocompatibility of Surgical Mesh*, 89 BRITISH J. OF SURGERY 1043, 1048 (2002).

of light microscopy and certain histological stains—do not permit him, or even a neuropathologist, to make causal conclusions regarding pain. *See* Mot. at 14–17.

Plaintiffs attempt to avoid Ethicon’s arguments, which are based on expert reports submitted by Ethicon’s neuropathologists, by claiming that they amount to nothing more than “conflicting opinions” by the parties’ experts. Resp. at 19. Plaintiffs apparently fail to grasp the fact that Ethicon challenged Dr. Michaels’s methodology, not merely his conclusions. *See* Mot. at 14–17.

Based on the opinions and testimony of neuropathologists—who, unlike Dr. Michaels, have specialized education, training, and experience in the identification of nerves and nerve components, as well as the diagnosis of nerve-related complications—Ethicon explained that Dr. Michaels’s opinions are not based on sound scientific methods or medical facts. *See id.*

In failing to address any of Ethicon’s specific arguments, Plaintiffs offer no explanation as to how the numerous methodological flaws outlined in the Motion could be construed as mere differences of opinion. Indeed, even a cursory review of the expert reports submitted by Drs. Vogel and McClendon demonstrates that their opinions go well beyond “conflicting opinions.”

V. Dr. Michaels’s Alternative-Design Opinions Are Unreliable, as the Nease Decision Makes Clear.

As Ethicon states in its Motion, Dr. Michaels’s alternative-design opinions are unreliable, because they are not supported by reliable testing or scientific literature. Mot. at 17–19. In response, Plaintiffs do not actually cite to any testing, literature, or other evidence supporting the reliability of Dr. Michaels’s alternative-design opinions. Instead, they simply note that “the Nease Court acknowledged that no single factor, even testing, is dispositive.” Resp. at 19. However, Plaintiffs do not explain what these other factors are or how they support the reliability of Dr. Michaels’s alternative-design theories. Dr. Michaels’s alternative-design opinions are

untested and unsupported by the peer-reviewed literature, and the Court should accordingly exclude them as unreliable. *See* Mot. at 17–19.

CONCLUSION

For the reasons set forth above and in Ethicon’s Motion, the Court should exclude the opinions and testimony of Dr. Paul Michaels.

Respectfully submitted,

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**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: WAVE 4 CASES LISTED IN MOTION EXHIBIT A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

CERTIFICATE OF SERVICE

I hereby certify that on May 3, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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